(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 348 375 A1

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
01.10.2003 Bulletin 2003/40

(51) Int Cl.7: **A61B 5/05**, A61N 1/365

(21) Application number: 03003108.2

(22) Date of filing: 13.02.2003

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT SE SI SK TR
Designated Extension States:
AL LT LV MK RO

(30) Priority: 25.03.2002 SE 0200922

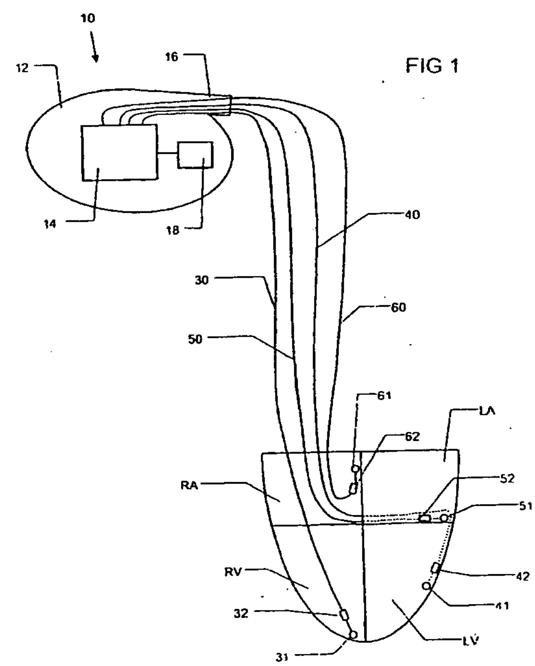
(71) Applicant: St. Jude Medical AB
175 84 Järfälla (SE)

(72) Inventors:
- Holmström, Nils
175 57 Järfälla (SE)
- Norlin, Anna
114 22 Stockholm (SE)
- Dahlberg, Kenneth
112 26 Stockholm (SE)
- Obel, Martin
182 33 Danderyd (SE)

(54) **A heart monitoring device, a system including such a device and a manner of using the system**

(57) The invention concerns a heart monitoring device (10) comprising a control circuit (14). The control circuit (14) is able to derive an impedance value (Z) indicative of the impedance between different electrode surfaces (31, 32, 41, 42). Furthermore, the control circuit (14) is arranged to determine and monitor a negative rate of change (dZ_2/dt) of the impedance value (Z) and to determine whether said negative rate of change, or its absolute value, increases or decreases over a plurality of heart cycles. Alternatively, or additionally, the control circuit (14) may determine and monitor a relationship between a positive rate of change (dZ_1/dt) and a negative rate of change (dZ_2/dt) of the impedance value (Z). The invention also concerns a system including such a device (10) and a manner of using such a system. The invention can, in particular, be used to detect and treat a diastolic dysfunction of a heart.

FIG 1



EP 1 348 375 A1

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

1. Field of the invention

[0001] The present invention relates to a heart monitoring device, to a system including such a device and to a manner of using the system. The device may be used to monitor the performance of a heart of a human or animal being. The device may also be arranged to deliver electrical stimulation pulses to the heart.

2. Description of the prior art

[0002] Several different devices for monitoring the performance of a heart are known. Often these devices are also able to deliver stimulation pulses to the heart. Such heart stimulation devices, or pacers, are normally arranged to stimulate the right ventricle of the heart. It is also known to stimulate the left ventricle. In particular for the treatment of congestive heart failure (CHF) or other severe cardiac failures, it is known to stimulate the left ventricle, or both ventricles, in order to optimise the hemodynamic performance of the heart. Some of these monitoring or stimulation devices are arranged to sense an impedance between electrode surfaces which are positioned in or at the heart and which are connected to the device. The sensed impedance may be used to control different pacing parameters.

[0003] US-A-4 733 667 describes a cardiac stimulator apparatus arranged with a lead that is preferably positioned in the right ventricle. The lead has a plurality of electrodes. The apparatus generates a signal corresponding to the impedance between two electrodes. The apparatus also includes a differentiator that produces a first derivative of said signal. The apparatus also has a peak detector where the peak value of the first derivative is captured on a beat-by-beat basis. The variation of this peak value is used to control the pacing rate. The pacing rate is thereby adapted to the level of exercise of the patient carrying the cardiac stimulator.

[0004] EP-A-591 642 describes a rate-responsive heart stimulator device with a tip and ring electrode positioned in a ventricle of the heart. The device is arranged to measure an impedance between said tip and ring electrodes and to produce a corresponding impedance signal. The signal is filtered and a differentiator produces the derivative of this signal. The minimum of this derivative is sensed. When the derivative increases after having passed the minimum, the signal is compared in a comparator to a threshold value. When the derivative reaches the threshold value, a control signal is generated, which after a preset delay results in the emission of a stimulation pulse. In this manner the stimulation rate is controlled. According to the document, this heart stimulator in essential respects imitates the function of a normal heart.

[0005] US-A-5 720 768 describes different possible electrode positions in order to stimulate or sense the different chambers of the heart.

[0006] US-5-154 171 describes the use of impedance values to control the pacing rate. The pacer described in this document is only arranged to stimulate the right side of the heart.

[0007] US-A-6 070 100 describes that electrodes may be positioned in both the left and the right atrium as well in the left and the right ventricle. The document describes the possibility of sensing the impedance between different electrodes. The sensed impedance values may be used to improve the cardiac output. The document mentions that a linear relationship exists between the peak dz/dt and the peak ejection rate.

[0008] US 2001/0012953 A1 describes bi-ventricular pacing. An impedance may be measured between electrodes on the right and the left sides of the heart. The variation of the impedance with time is detected. The detected impedance variation may be used in order to synchronise the contraction of the ventricles.

[0009] US 2001/0021864 A1 describes different manners of using the proximal and distal electrodes of different leads in order to inject a current and to measure an impedance. The measured impedance value may be used in order to maximise the cardiac flow.

[0010] It is often difficult to determine the specific cause of a heart problem. For example, for a patient suffering from congestive heart failure (CHF) it is often difficult to know what causes this problem. The cause may be a systolic dysfunction or a diastolic dysfunction. The systole relates to the contraction of the heart, i.e. the pumping phase. Diastole relates to the phase when the heart is relaxed, i.e. when the ventricles are being filled with blood. In particular it is often difficult to be able to determine a diastolic dysfunction of the heart.

SUMMARY OF THE INVENTION

[0011] An object of the present invention is to provide a device which makes it possible to determine, inter alia, a diastolic dysfunction of the heart. A further object is to provide such a device which uses an impedance measurement when monitoring the function of the heart. A still further object is to provide such a device which in a relatively simple manner is able to determine a heart dysfunction. According to advantageous embodiments of the invention, the device may also be arranged to deliver stimulation pulses to the heart in order to treat the determined dysfunction. The invention also provides a system including such a device and a manner of using such a system.

[0012] The objects of the invention are achieved by a heart monitoring device comprising:

a control circuit, the control circuit being adapted to be electrically connected to a first electrode surface arranged at a first position of the heart and to a sec-

ond electrode surface arranged at a second position of the heart,

the control circuit also being arranged to at least enable the following:

a) derive an impedance value indicative of the impedance between said first and second electrode surfaces,
b) determine a negative rate of change of said impedance value at a first point or portion of a heart cycle,
c) monitor said negative rate of change over a plurality of heart cycles,
d) determine whether said negative rate of change, or its absolute value, increases or decreases over said plurality of heart cycles.

[0013] By determining an appropriate impedance value and by monitoring the mentioned negative rate of change of the impedance value, an indication of the diastolic function of the heart may be achieved. This will be explained below. With such a device it is thus possible to monitor and detect a possible diastolic dysfunction of the heart. Thereby a basis for treatment of the heart may be obtained. By determining whether this rate of change increases or decreases it is possible to decide whether the diastolic function of the heart is improved or gets worse.

[0014] According to an embodiment, the control circuit is arranged to also enable the following: deliver electrical stimulation pulses, via one or more electrical leads, to said heart. Preferably, the control circuit is arranged to control the delivery of said electrical stimulation pulses in response to said monitored value of the negative rate of change. By controlling the delivery of electrical stimulation pulses in response to the monitored value, a suitable treatment of the heart may be carried out.

[0015] According to a further embodiment, the control circuit is arranged to also enable the following: control the delivery of said electrical stimulation pulses such that the diastolic time quotient is controlled in response to said monitored value of the negative rate of change (for a definition of the diastolic time quotient, see later in this description). Preferably, said diastolic time quotient is increased if the absolute value of said negative rate of change decreases. The diastolic time quotient is preferably decreased if the absolute value of said negative rate of change increases. By setting appropriate pacing parameters in response to the monitored value, an appropriate diastolic time quotient is achieved and thereby an appropriate electrical stimulation of the heart is obtained. The diastolic time quotient may thus be controlled such that the heart has an appropriate time to relax such that the ventricles can be filled with blood.

[0016] According to a still further embodiment, said control circuit is arranged to enable, within the same cycle of the heart, the delivery of stimulation pulses suitable to stimulate both the left and the right ventricles of the heart. When for example treating a patient suffering from CHF it is particularly important to stimulate both the ventricles of the heart in order to improve the heart condition of the patient.

[0017] According to a further embodiment, the device comprises a housing, wherein the control circuit is positioned in said housing and wherein said device is designed to be implantable in a human or animal being. The device may thus for example constitute an implantable pacer.

[0018] According to a further realisation of the invention, the above objects are achieved by a heart monitoring device comprising:

a control circuit, the control circuit being adapted to be electrically connected to a first electrode surface arranged at a first position of the heart and to a second electrode surface arranged at a second position of the heart,

the control circuit also being arranged to at least enable the following:

a) derive an impedance value indicative of the impedance between said first and second electrode surfaces,
b) determine a negative rate of change of said impedance value at a first point or portion of a heart cycle,
c) determine a positive rate of change of said impedance value at a second point or portion of the heart cycle,
d) determine a relationship between said positive rate of change and said negative rate of change,
e) monitor said relationship over a plurality of heart cycles.

[0019] According to this realisation of the invention, the device is thus arranged to monitor the mentioned relationship between the positive and negative rates of change. By monitoring this relationship, the monitored values are less sensitive to other factors, such as amplitude variations of the impedance due to the breathing of the person or animal in question or variations in temperature. However, it should be pointed out that it is also within the scope of the invention to monitor both the mentioned relationship and the negative rate of change as described above.

[0020] According to a preferred embodiment, said control circuit is arranged such that said relationship comprises the ratio between said positive rate of change and said negative rate of change. Preferably, the control circuit is arranged to also enable the following: determine whether said ratio, or its absolute value, increases or decreases over said plurality of heart cycles. By monitoring said ratio it is possible to determine whether the diastolic function of the heart is improved or gets worse. It should be noted that when in this document it is men-

tioned that the ratio between the positive rate of change and the negative rate of change is monitored, this is meant to include the possibility that instead the inverse of this ratio is monitored. An increase in the mentioned ratio is of course equivalent to a decrease of the inverse, and vice versa.

[0021] According to another embodiment, the control circuit is arranged to also enable the following: deliver electrical stimulation pulses, via one or more electrical leads, to said heart. It is thereby possible to deliver suitable stimulation pulses in order to improve the heart condition.

[0022] Also according to this realisation of the invention, the control circuit may be arranged to also enable the following: control the delivery of said electrical stimulation pulses in response to said monitored relationship. Preferably, the diastolic time quotient is controlled in response to said monitored relationship. In an analogous manner to what has been described above, it is thus possible to adjust the diastolic time quotient in response to the monitored' relationship.

[0023] According to a preferred embodiment, the diastolic time quotient is increased if the absolute value of the ratio between the positive rate of change and the negative rate of change increases. Analogously, the diastolic time quotient may be decreased if the absolute value of the ratio between the positive rate of change and the negative rate of change decreases. Through these features, the heart condition may be improved.

[0024] Also according to this realisation of the invention, the control circuit may be arranged to enable, within the same cycle of the heart, the delivery of stimulation pulses suitable to stimulate both the left and the right ventricles of the heart. The control circuit may be positioned in a housing, wherein said device is designed to be implantable in a human or animal being. The device may thus for example constitute an implantable pacer which may be arranged to treat, inter alia, a patient suffering from CHF.

[0025] The objects of the invention are also achieved by a heart monitoring system comprising a heart monitoring device according to any of the preceding embodiments and a first lead comprising at least said first electrode surface and a second lead comprising at least said second electrode surface, wherein said first and second leads are connected to the heart stimulating device such that said first and second electrode surfaces are connected to said control circuit. The system thus comprises the device with attached first and second leads.

[0026] The invention also concerns manners of using such a system as specified in the claims 20 to 27 With these manners of using the system, a possible diastolic dysfunction of said heart may be monitored and treated. These manners of using the system thus concern the treatment of a human or animal being with the help of the system. Through such a treatment, inter alia, the heart condition of a patient suffering from CHF may be improved. In particular, the treatment may be carried out in response to a detected diastolic dysfunction of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027]

Fig 1 shows schematically a heart monitoring device connected to leads with electrode surfaces positioned in a heart.

Fig 2 shows schematically the variation of the impedance with time.

Fig 3 shows the same representation as Fig 2 but with an additional curve indicating a diastolic dysfunction.

Fig 4 shows the same representation as Fig 2 but with an addition curve indicating a systolic dysfunction.

Fig 5 shows a flow chart of the function of the heart monitoring device according to an embodiment of the invention.

Fig 6 shows a flow chart of the function of the heart monitoring device according to another embodiment of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0028] An embodiment of the invention will now first be described with reference to Fig 1. Fig 1 schematically shows a heart monitoring device 10. According to a preferred embodiment, the device 10 comprises a housing 12. The device may be designed such that it can be implanted in a human or animal being. A control circuit 14 is arranged in the housing 12. The device 10 has a connector portion 16 to which a plurality of leads 30, 40, 50, 60 may be attached. In the shown embodiment there are thus four leads 30, 40, 50, 60 attached to the device 10. However, the number of leads may be less than four. In the shown embodiment, the first lead 30 comprises a distal electrode 31 (also called tip electrode) and a proximal electrode 32 (also called ring electrode). In the shown embodiment, the lead 30 is thus bipolar. However, it is also possible that one or more leads are unipolar, i.e. that it only comprises one electrode surface. The lead 30 includes electrical conductors (not shown) through which the electrode surfaces 31, 32 are connected to the control circuit 14. The control circuit 14 is also adapted to be connected to a second lead 40, which has corresponding electrode surfaces 41, 42.

[0029] The device 10 may also be arranged such that it is connectable to further leads. Fig 1 thus shows a third lead 50 with electrode surfaces 51, 52 and a fourth lead 60 with electrode surfaces 61, 62.

[0030] Fig 1 also schematically shows a heart comprising a right atrium RA, a right ventricle RV, a left atrium LA and a left ventricle LV. In the illustrated embodiment the electrodes 31, 32 are positioned in the heart near the apex of the right ventricle RV. The lead 40 is

positioned such that the electrodes 41, 42 may be used for emitting stimulating pulses to the left ventricle LV. The lead 40 may for example be introduced through the right atrium RA, via the coronary sinus into the middle or great cardiac vein. In the shown embodiment, a third lead 50 is introduced such that the electrodes 51, 52 are positioned in the coronary sinus, a fourth lead 60 is introduced such that the electrodes 61, 62 are positioned in the right atrium RA. These manners of positioning the different leads 30, 40, 50, 60 are well known to a person skilled in the art.

[0031] The control circuit 14 is arranged to derive an impedance value Z indicative of the impedance Z between two electrode surfaces. According to an advantageous embodiment, the impedance Z is sensed between electrode surfaces of two different leads. For example, the control circuit 14 may via the connector portion 16 be arranged to sense an impedance between an electrode surface 31, 32 of the first lead 30 and an electrode surface 41, 42 of the second lead 40. The impedance may be sensed between the ring or tip electrode surfaces as described in some of the above mentioned documents. According to an advantageous embodiment, the impedance value Z may for example be sensed between the electrode surfaces 32 and 42. The impedance may for example be measured by injecting a current and measuring a voltage in response to the injected current. Examples of how to measure the impedance are given in some of the above mentioned documents

[0032] According to an embodiment of the invention, the control circuit 14 is also arranged to deliver electrical stimulation pulses, via one or more of the leads 30, 40, 50, 60, to the heart. The device according to this embodiment thus functions as a pacer. Such a pacer 10 is well known to a person skilled in the art and will therefore not be described in all its details here. The device 10 may be arranged such that the control circuit 14 is able to deliver stimulation pulses, within the same cycle of the heart, suitable to stimulate both the left LV and the right RV ventricles of the heart. Such a device 10 may be used in order to treat, for example, a patient suffering from CHF.

[0033] The device 10 may also be arranged to receive signals indicating the activity level of a living being into which the device 10 is implanted. Such signals may for example be produced by an activity sensor 18 included within the housing 12. Different kinds of activity sensors 18 are known to a person skilled in the art. Such an activity sensor 18 may be used to control different pacing parameters.

[0034] According to the invention, the control circuit 14 is arranged to enable the determination of a negative rate of change dZ_2/dt.

[0035] The impedance variation during a heart cycle HC will now be explained with reference to Fig 2, 3 and 4. Fig 2 thus shows schematically the variation of the impedance Z with time t during a heart cycle HC. The impedance value here shown may be the impedance measured across the left ventricle LV of the heart. Such an impedance value may thus for example be obtained between the electrode surfaces 32 and 42 in Fig 1. The impedance value Z is low when the ventricle LV is filled with blood. During the systolic phase, when the ventricle LV pumps out the blood, the impedance Z increases to a maximum value, whereafter the impedance Z sinks when the ventricle LV fills with blood during the diastolic phase. Fig 2 shows an indicated positive rate of change dZ_1/dt of the sensed impedance value Z during the systolic phase. dZ_2/dt represents a negative rate of change during the diastolic phase. dZ_1/dt and dZ_2/dt may be defined in different manners. For example, dZ_1/dt may be the maximum of the derivative dZ/dt during the heart cycle. However, dZ_1/dt may also be defined as an average positive rate of change during a certain portion of the heart cycle HC. Independently of how the positive rate of change is defined, this rate of change indicates the steepness of the curve Z during the systolic phase. dZ_2/dt may be defined in analogous manners. Independently of exactly how dZ_2/dt is defined, it represents the steepness of the curve Z during the diastolic phase.

[0036] Fig 3 shows the same curve Z as Fig 2. Fig 3 also shows, with hatched lines, a second impedance curve 70. This curve 70 shows the impedance variation during a heart cycle when the diastolic function of the heart in question has become worse. As can be seen in Fig 3, dZ_1/dt is very similar to dZ_1/dt in the case of the curve in Fig 2. However, the curve 70 is more flat in the diastolic phase. Therefore, dZ_2/dt is now not as steep as according to the curve Z in Fig 2. The steepness of the negative rate of change dZ_2/dt may thus be used as an indication of the diastolic function of the heart.

[0037] Fig 4 shows the same curve Z as Fig 2. Additionally, Fig 4 shows in hatched lines a curve 80. This curve 80 represents the impedance value during a heart cycle HC when the systolic function of the heart has become worse compared to the situation in Fig 2. The negative rate of change dZ_2/dt is here quite similar to that of the curve Z in Fig 2. However, the positive rate of change of dZ_1/dt is now less steep than in Fig 2. The steepness of dZ_1/dt in Fig 4 thus indicates that the systolic function of the heart has become worse compared to the situation in Fig 2.

[0038] Fig 5 shows a schematic flow chart of the operation of a device 10 according to the invention. According to this embodiment, the control circuit 14 is thus arranged to derive an impedance value indicative of the impedance between first and second electrode surfaces, for example between the mentioned electrode surfaces 32 and 42. dZ_2/dt is determined. The determined value of dZ_2/dt is stored. dZ_2/dt is monitored during a number of heart cycles HC. dZ_2/dt may be continuously monitored all the time. Alternatively, it is possible monitor dZ_2/dt only during certain periods. Since dZ_2/dt is monitored, it is possible to determine

whether dZ_2/dt increases or decreases. It is thereby possible to derive information about the diastolic function of the heart. In case the device 10 is arranged to deliver stimulation pulses to the heart, the diastolic time quotient may be controlled in response to the determination whether dZ_2/dt increases or decreases. The diastolic time quotient can be defined as: $t_{diastole}/(t_{systole}+t_{diastole})$ where $t_{systole}$ is the time of the systolic part of the heart cycle and $t_{diastole}$ is the time of the diastolic part of the heart cycle. The diastolic time quotient is thus related to the diastolic time in a pacer-controlled heart. The diastolic time quotient may thus be controlled or varied by controlling different pacing parameters, for example the so-called AV-interval and/or the pacing rate and/or the VV-interval in a device which is able to deliver stimulating pulses to both the ventricles of the heart. If a worsening diastolic function of the heart is detected, it is thus possible to increase the diastolic time quotient in order to give the ventricles more time to be filled with blood.

[0039] It should be mentioned that the controlled value dZ_2/dt may also be the absolute value of dZ_2/dt in order to always have a positive value. The control circuit 14 may thus be arranged to increase the diastolic time quotient if the absolute value of dZ_2/dt decreases. The control circuit 14 may be arranged to decrease the diastolic time quotient if the absolute value of dZ_2/dt increases.

[0040] Fig 6 illustrates schematically a flow chart of the operation of the device 10 according to another embodiment of the invention. Also according to this embodiment, an impedance value Z is derived.

[0041] The impedance value Z is indicative of the impedance between electrode surfaces, for example between the electrode surfaces 32 and 42. According to this embodiment, both dZ_2/dt and dZ_1/dt are determined. A relationship between the determined values is determined. This relationship may be the ratio $(dZ_1/dt)/(dZ_2/dt)$. Alternatively, the absolute value of this ratio may be determined. The value of the relationship or ratio is stored. This relationship is monitored over a number of heart cycles. This can be done in different manners as indicated above in connection with Fig 5. The mentioned ratio is less sensitive to external influence on the impedance value Z than if only the negative change of rate dZ_2/dt is monitored. The monitored value of $(dZ_1/dt)/(dZ_2/dt)$ indicates the function of the heart. It may be determined whether the absolute value of the mentioned ratio increases or decreases. The diastolic time quotient may be controlled in response to the determined ratio in an analogous manner to that which has been described above in connection with Fig 5. Also according to this embodiment, it is thus possible to increase or decrease the diastolic time quotient in response to the monitored relationship. If the absolute value of the mentioned ratio increases, the diastolic time quotient may be increased and vice versa. Also according to this embodiment, the control circuit 14 may be arranged to enable the delivery of stimulation pulses to both the left LV and the right RV ventricles.

[0042] It should be mentioned that it is of course possible to arrange the control circuit 14 to monitor both the mentioned ratio and the value dZ_2/dt. It is of course possible to also at the same time monitor the value dZ_1/dt. By the combined monitoring of these different values, a clear indication of whether the systolic function or the diastolic function of the heart changes is obtained. At the same time the influence on the impedance variation Z by external factors is reduced since the mentioned ratio is taken into account.

[0043] A heart monitoring system according to the invention is also illustrated in Fig 1. This system comprises the device 10 according to any of the above embodiments together with at least a first lead 30 and a second lead 40. These leads 30, 40 are connected to the device 10 such that at least a first 31, 32 and a second 41, 42 electrode surface are connected to the control circuit 14. According to a manner of using such a system, the first 31, 32 and the second 41, 42 electrode surfaces are positioned in or at a heart of a human or animal being. The electrode surfaces 31, 32, 41, 42 may be introduced into the heart in the above described manner. The system is used such that the value dZ_2/dt is monitored as discussed in connection with Fig 5. According to an alternative manner of using the system, the system is used such that the ratio $(dZ_1/dt)/(dZ_2/dt)$ is monitored in the manner described in connection with Fig 6. Advantageously, the electrode surfaces 31, 32, 41, 42 are positioned such that the impedance value Z is measured across at least a part of one of the first RV and second LV ventricles of the heart. Preferable, the impedance value Z is measured across the left ventricle LV of the heart. The system is preferably used to monitor a possible diastolic dysfunction of the heart as has been described above. The system is particularly suitable to monitor a possible diastolic dysfunction in a patient suffering from CHF. The system may be set up to deliver electrical stimulation pulses to the heart and to control the delivery of these pulses such that the diastolic time quotient is controlled. Preferably, the system is used such that electrical stimulation pulses are delivered to both the ventricles RV, LV of the heart.

[0044] The invention is not limited to the described embodiments but may be varied and modified within the scope of the following claims.

[0045] Different modifications are thus possible. For example, although the above described embodiments are directed to sensing an impedance value Z across the left ventricle LV of the heart is instead possible to detect an impedance value across the right ventricle RV. The mentioned rates of change may in this case be used to control the diastolic time quotient also in case the device 10 is arranged to deliver stimulation pulses only to the right side of the heart.

Claims

1. A heart monitoring device (10) comprising:

   a control circuit (14), the control circuit (14) being adapted to be electrically connected to a first electrode surface (31, 32) arranged at a first position of the heart and to a second electrode surface (41, 42) arranged at a second position of the heart,
   the control circuit (14) also being arranged to at least enable the following:

   a) derive an impedance value (Z) indicative of the impedance between said first (31, 32) and second (41, 42) electrode surfaces,
   b) determine a negative rate of change (dZ_2/dt) of said impedance value (Z) at a first point or portion of a heart cycle (HC),
   c) monitor said negative rate of change (dZ_2/dt) over a plurality of heart cycles (HC),
   d) determine whether said negative rate of change (dZ_2/dt), or its absolute value, increases or decreases over said plurality of heart cycles.

2. A heart monitoring device (10) according to claim 1, wherein the control circuit (14) is arranged to also enable the following:

   deliver electrical stimulation pulses, via one or more electrical leads (30, 40, 50, 60), to said heart.

3. A heart monitoring device (10) according to claim 2, wherein the control circuit (14) is arranged to also enable the following:

   control the delivery of said electrical stimulation pulses in response to said monitored value of the negative rate of change (dZ_2/dt).

4. A heart monitoring device (10) according to claim 3, wherein the control circuit (14) is arranged to also enable the following:

   control the delivery of said electrical stimulation pulses such that the diastolic time quotient is controlled in response to said monitored value of the negative rate of change (dZ_2/dt).

5. A heart monitoring device (10) according to claim 4, wherein said control circuit (14) is arranged to increase said diastolic time quotient if the absolute value of said negative rate of change (dZ_2/dt) decreases.

6. A heart monitoring device (10) according to claim 4 or 5, wherein said control circuit (14) is arranged to decrease the diastolic time quotient if the absolute value of said negative rate of change (dZ_2/dt) increases.

7. A heart monitoring device (10) according to any of the preceding claims, wherein said control circuit (14) is arranged to enable, within the same cycle of the heart, the delivery of stimulation pulses suitable to stimulate both the left (LV) and the right (RV) ventricles of the heart.

8. A heart monitoring device (10) according to any of the preceding claims, comprising a housing (12), wherein said control circuit (14) is positioned in said housing (12) and wherein said device (10) is designed to be implantable in a human or animal being.

9. A heart monitoring device (10) comprising:

   a control circuit (14), the control circuit (14) being adapted to be electrically connected to a first electrode surface (31, 32) arranged at a first position of the heart and to a second electrode surface (41, 42) arranged at a second position of the heart,
   the control circuit (14) also being arranged to at least enable the following:

   a) derive an impedance value (Z) indicative of the impedance between said first (31, 32) and second (41, 42) electrode surfaces,
   b) determine a negative rate of change (dZ_2/dt) of said impedance value (Z) at a first point or portion of a heart cycle (HC),
   c) determine a positive rate of change (dZ_1/dt) of said impedance value (Z) at a second point or portion of the heart cycle (HC),
   d) determine a relationship between said positive rate of change (dZ_1/dt) and said negative rate of change (dZ_2/dt),
   e) monitor said relationship over a plurality of heart cycles (HC).

10. A heart monitoring device (10) according to claim 9, wherein said control circuit (14) is arranged such that said relationship comprises the ratio between said positive rate of change (dZ_1/dt) and said negative rate of change (dZ_2/dt).

11. A heart monitoring device (10) according to claim 10, wherein the control circuit (14) is arranged to also enable the following:

   determine whether said ratio, or its absolute

value, increases or decreases over said plurality of heart cycles (HC).

12. A heart monitoring device (10) according to any of the claims 9-11, wherein the control circuit (14) is arranged to also enable the following:

    deliver electrical stimulation pulses, via one or more electrical leads (30, 40, 50, 60), to said heart.

13. A heart monitoring device (10) according to claim 12, wherein the control circuit (14) is arranged to also enable the following:

    control the delivery of said electrical stimulation pulses in response to said monitored relationship.

14. A heart monitoring device (10) according to claim 13, wherein the control circuit (14) is arranged to also enable the following:

    control the delivery of said electrical stimulation pulses such that the diastolic time quotient is controlled in response to said monitored relationship.

15. A heart monitoring device (10) according to claim 14, wherein said control circuit (14) is arranged to increase the diastolic time quotient if the absolute value of the ratio between the positive rate of change (dZ_1/dt) and the negative rate of change (dZ_2/dt) increases.

16. A heart monitoring device (10) according to claim 14 or 15, wherein said control circuit (14) is arranged to decrease the diastolic time quotient if the absolute value of the ratio between the positive rate of change (dZ_1/dt) and the negative rate of change (dZ_2/dt) decreases.

17. A heart monitoring device (10) according to any of claims 9-16, wherein said control circuit (14) is arranged to enable, within the same cycle of the heart, the delivery of stimulation pulses suitable to stimulate both the left (LV) and the right (RV) ventricles of the heart.

18. A heart monitoring device (10) according to any of the claims 9-17, comprising a housing (12), wherein said control circuit (14) is positioned in said housing (12) and wherein said device (10) is designed to be implantable in a human or animal being.

19. A heart monitoring system comprising a heart monitoring device (10) according to any of the preceding claims and a first lead (30) comprising at least said first electrode surface (31, 32) and a second lead (40) comprising at least said second electrode surface (41, 42), wherein said first (30) and second (40) leads are connected to the heart stimulating device (10) such that said first (31, 32) and second (41, 42) electrode surfaces are connected to said control circuit (14).

20. A manner of using a heart monitoring system according to claim 19, wherein said first (31, 32) and second (41,42) electrode surfaces are positioned in or at a heart of a human or animal being and wherein at least the steps a) to d) of claim 1 are performed.

21. A manner of using a heart monitoring system according to claim 19, wherein said first (31, 32) and second (41,42) electrode surfaces are positioned in or at a heart of a human or animal being and wherein at least the steps a) to e) of claim 9 are performed.

22. A manner according to claim 20 or 21, wherein said first (31, 32) and second (41, 42) electrode surfaces are positioned such that the impedance value (Z) is measured across at least a part of one of the first (RV) and second (LV) ventricles of said heart.

23. A manner according to claim 22, wherein said ventricle, across which the impedance value is measured, is the left ventricle (LV) of the heart.

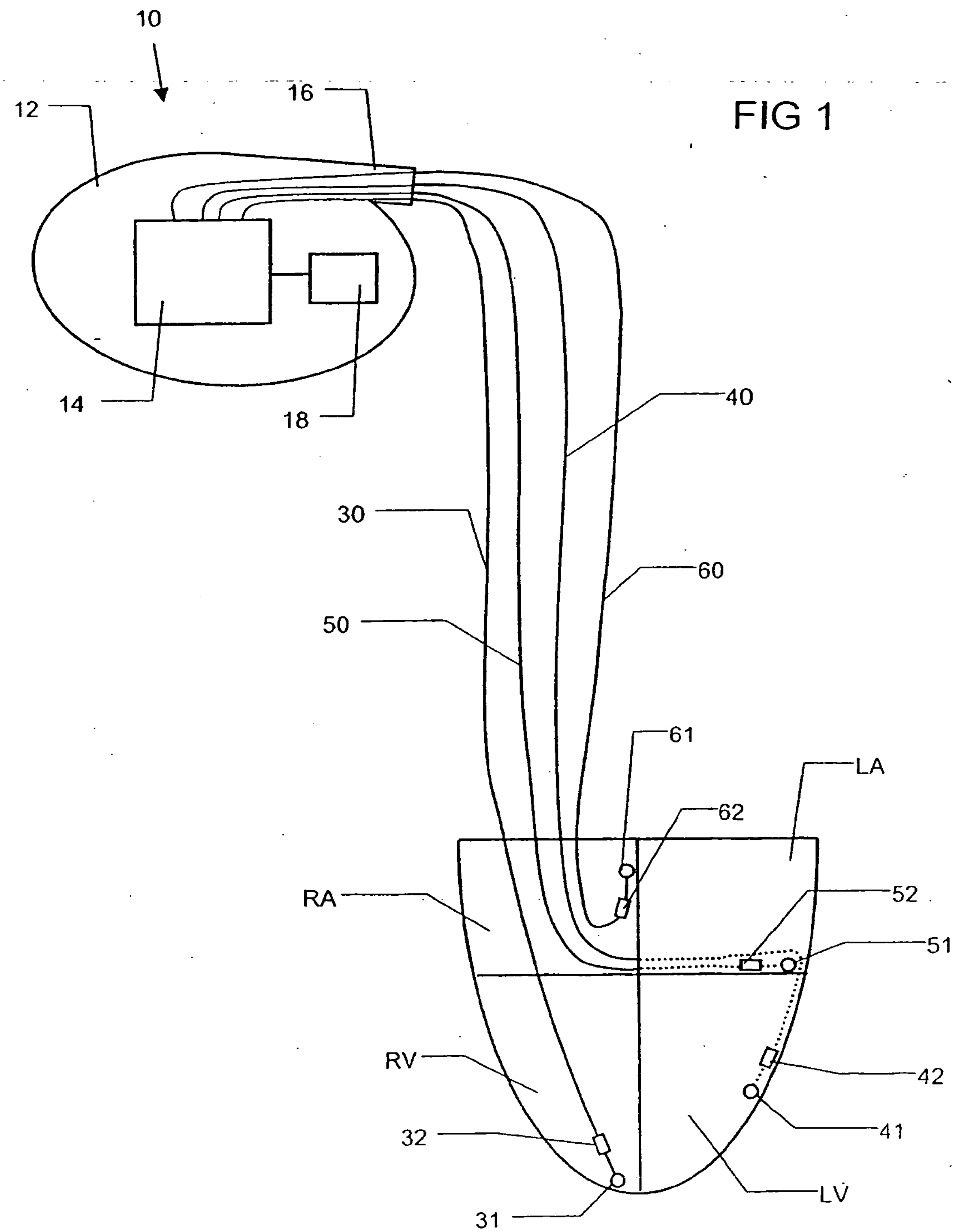
24. A manner according to any of the claims 20-23, wherein the system is used to monitor a possible diastolic dysfunction of said heart.

25. A manner according to claim 24, wherein the system is used to monitor said possible diastolic dysfunction in a patient suffering from congestive heart failure (CHF).

26. A manner according to any of claims 24 or 25, wherein the system is used to deliver electrical stimulation pulses to said heart and to thereby control the delivery of said electrical stimulation pulses such that the diastolic time quotient is controlled.

27. A manner according to claim 26, wherein the system is used to deliver electrical stimulation pulses to both the ventricles (LV; RV) of said heart.

FIG 1



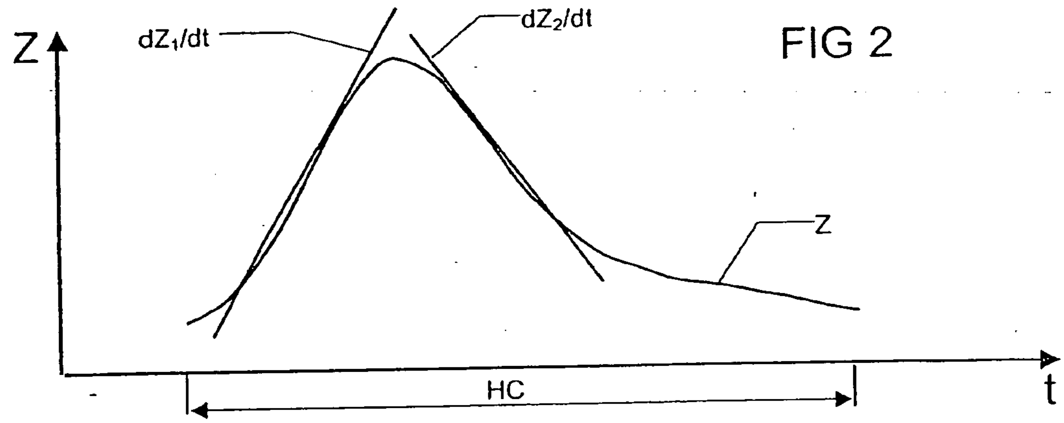


FIG 2

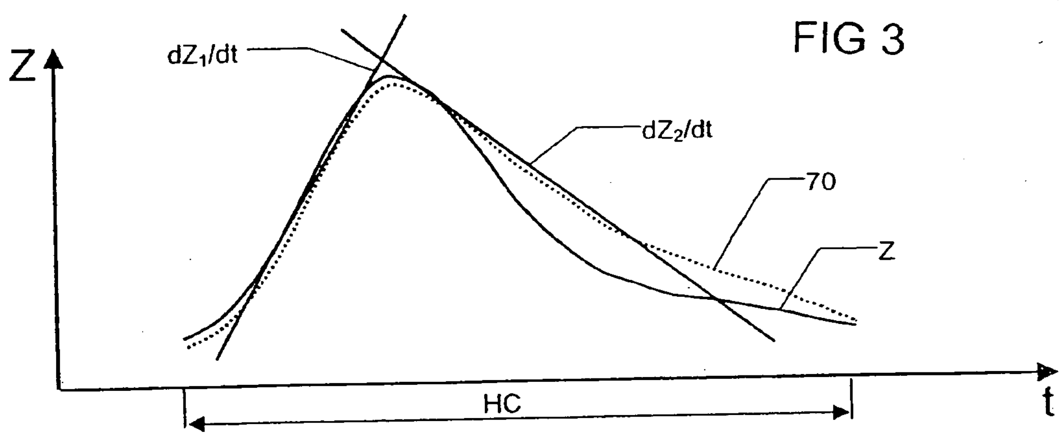


FIG 3

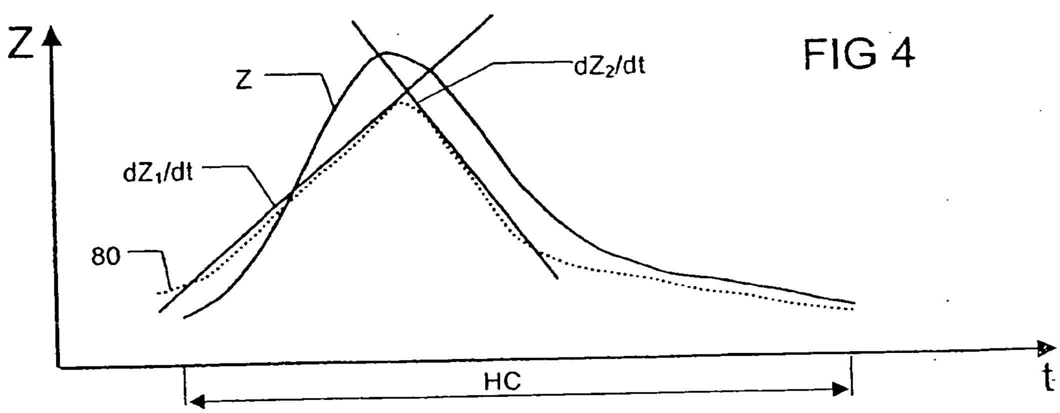


FIG 4

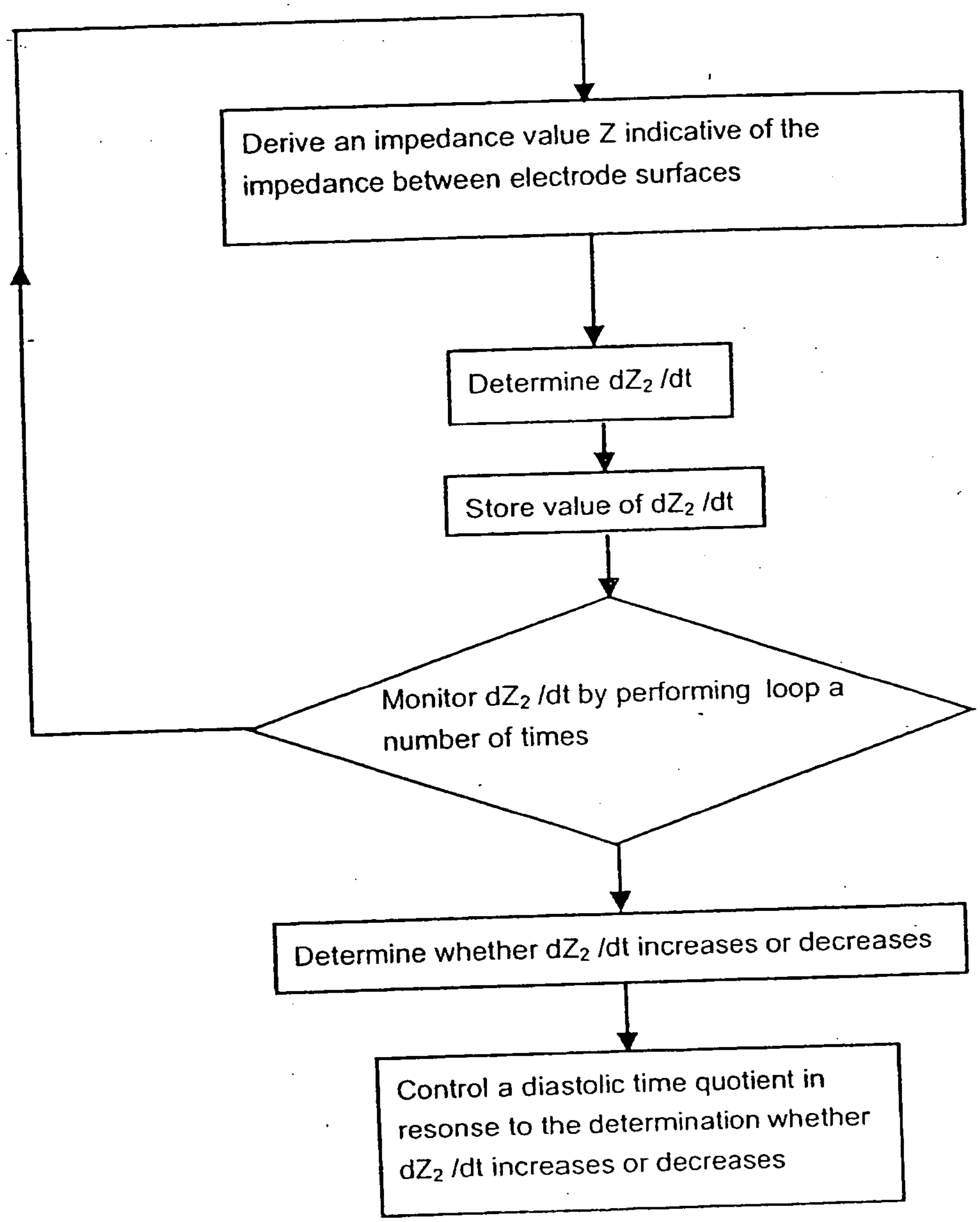

Derive an impedance value Z indicative of the impedance between electrode surfaces
Determine dZ_2/dt
Store value of dZ_2/dt
Monitor dZ_2/dt by performing loop a number of times
Determine whether dZ_2/dt increases or decreases
Control a diastolic time quotient in resonse to the determination whether dZ_2/dt increases or decreases

FIG 5

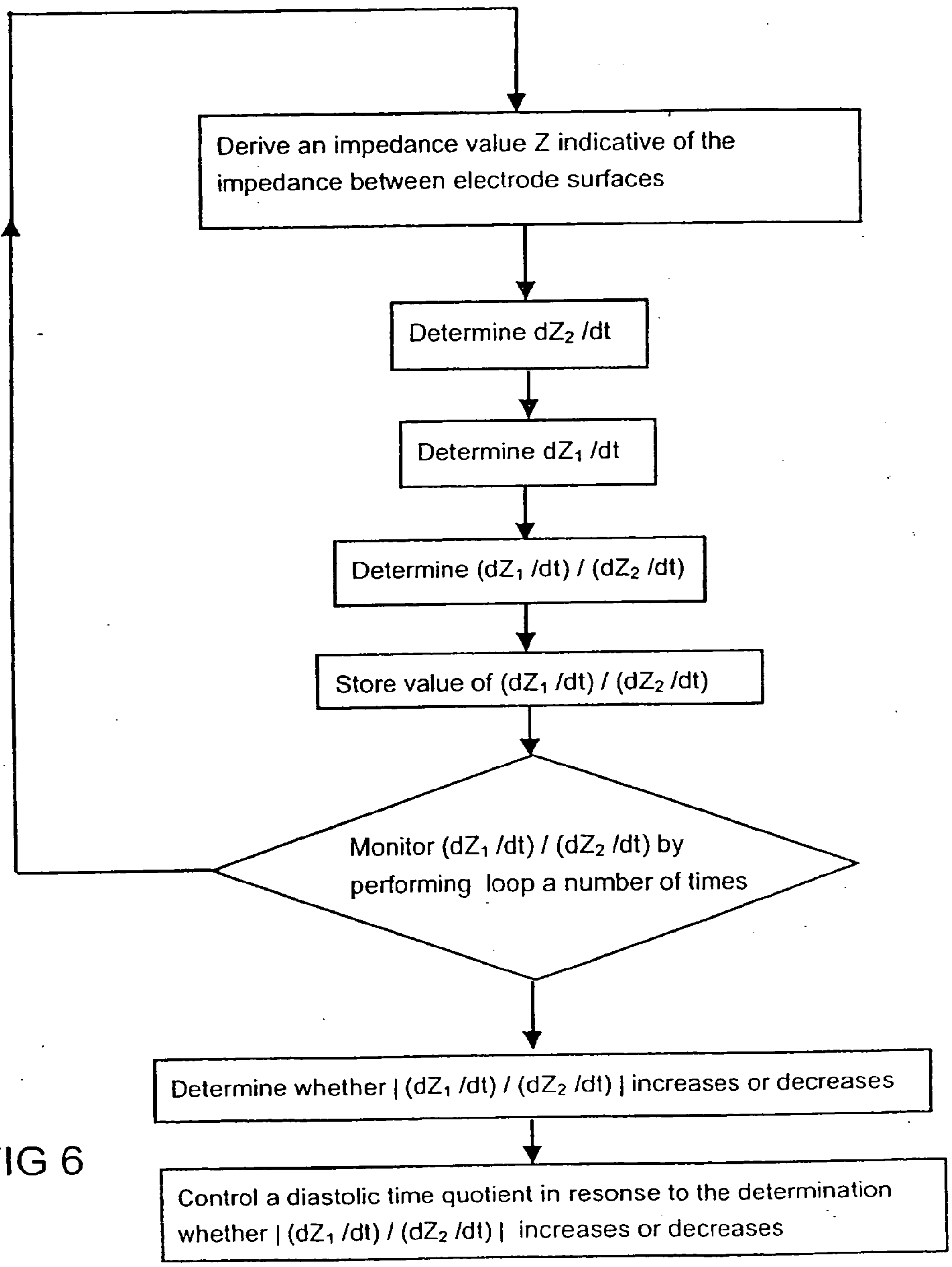

Derive an impedance value Z indicative of the impedance between electrode surfaces
Determine dZ_2 /dt
Determine dZ_1 /dt
Determine $(dZ_1/dt) / (dZ_2/dt)$
Store value of $(dZ_1/dt) / (dZ_2/dt)$
Monitor $(dZ_1/dt) / (dZ_2/dt)$ by performing loop a number of times
Determine whether $|(dZ_1/dt) / (dZ_2/dt)|$ increases or decreases
Control a diastolic time quotient in resonse to the determination whether $|(dZ_1/dt) / (dZ_2/dt)|$ increases or decreases

FIG 6

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 03 00 3108

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X A	US 5 235 976 A (SPINELLI JULIO C) 17 August 1993 (1993-08-17) * column 5, line 33 - line 42 * * column 6, line 39 - line 64 * ---	1-6,8,19 7	A61B5/05 A61N1/365
X A	WEISS S M ET AL: "Do changes in transcardiac impedance modulation correlate with haemodynamic status?" AUSTRALASIAN PHYSICAL & ENGINEERING SCIENCES IN MEDICINE / SUPPORTED BY THE AUSTRALASIAN COLLEGE OF PHYSICAL SCIENTISTS IN MEDICINE AND THE AUSTRALASIAN ASSOCIATION OF PHYSICAL SCIENCES IN MEDICINE. AUSTRALIA JUN 1992, vol. 15, no. 2, June 1992 (1992-06), pages 57-64, XP008019842 ISSN: 0158-9938 * page 58, section "Transcardiac Impedance Measurement * ---	9,12-16, 18,19 1,17	
A	WO 01 87410 A (PACESETTER INC) 22 November 2001 (2001-11-22) * page 16, line 20 - page 17, line 10 * --- -/--	1-9, 12-19	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61B A61N

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 July 2003	Knüpling, M

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

European Patent Office

INCOMPLETE SEARCH SHEET C

Application Number
EP 03 00 3108

Claim 20 implicitly contains the step of placing electrodes in or at a heart which is considered as surgery

----

Claim(s) not searched:
20-27

Reason for the limitation of the search (non-patentable invention(s)):

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 03 00 3108

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	US 5 505 209 A (REINING WILLIAM N) 9 April 1996 (1996-04-09) * column 7, line 59 - column 8, line 36 * -----	1-7, 9-17,19	

TECHNICAL FIELDS SEARCHED (Int.Cl.7)

EPO FORM 1503 03.82 (P04C10)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 03 00 3108

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-07-2003

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
US 5235976	A	17-08-1993	CA	2091708	A1	17-09-1994
			EP	0615770	A1	21-09-1994
			AU	3522493	A	29-09-1994
			DE	69323543	D1	25-03-1999
			DE	69323543	T2	08-07-1999
			ES	2130222	T3	01-07-1999
WO 0187410	A	22-11-2001	AU	6310801	A	26-11-2001
			WO	0187410	A2	22-11-2001
			US	2002002389	A1	03-01-2002
US 5505209	A	09-04-1996	DE	69530207	D1	08-05-2003
			EP	0771172	A1	07-05-1997
			WO	9601586	A1	25-01-1996

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82